

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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UNITEDHEALTHCARE INSURANCE :
COMPANY and UNITED HEALTHCARE :
SERVICES, INC., :

Plaintiffs, :

v. :

REGENERON PHARMACEUTICALS, INC., :
Defendant. :

OPINION AND ORDER

20 CV 10664 (VB)

-----X
HUMANA INC., :

Plaintiffs, :

v. :

REGENERON PHARMACEUTICALS, INC., :
Defendant. :

21 CV 6245 (VB)

-----X
Briccetti, J.:

Plaintiffs UnitedHealthcare Insurance Company and United Healthcare Services, Inc. (together, “United”), bring an action against defendant Regeneron Pharmaceuticals, Inc. (“Regeneron”), alleging Regeneron engaged in an illegal kickback scheme to promote a drug it manufactures called EYLEA. Plaintiff Humana Inc. (“Humana”) brings a separate action against Regeneron, making the same allegations.

Now pending are Regeneron’s motions to dismiss or, in the alternative, to stay both actions pending resolution of United States v. Regeneron Pharmaceuticals, Inc., No. 20cv11217 (D. Mass. filed June 24, 2020) (the “DOJ Action”). (United Doc. #32; Humana Doc. #20).¹

Although these cases are not formally consolidated, because Regeneron’s motions raise the same issues, the Court will address the motions together in the interest of judicial economy.

¹ This Opinion and Order references filings in the United case by (United Doc. #__), in the Humana case by (Humana Doc. #__), and in the DOJ Action by (DOJ Doc. #__).

For the following reasons, the motions to stay are GRANTED, and the motions to dismiss are TERMINATED without prejudice to refile when the stays in these cases are lifted.

The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1332.

BACKGROUND

Regeneron manufactures EYLEA, a drug that treats neovascular, or “wet,” age-related macular degeneration. EYLEA is administered by injection, and plaintiffs allege EYLEA must be administered “indefinitely” to be effective. (United Doc. #29 (“United Am. Compl.”) ¶¶ 28, 31; Humana Doc. #1 (“Humana Compl.”) ¶¶ 21, 23).

Plaintiffs insure and administer Medicare Advantage plans, also called Medicare Part C plans. Medicare is federally funded health insurance for seniors and people with certain disabilities, and Medicare Advantage plans “are offered by Medicare-approved private companies that must follow rules set by Medicare.” How Do Medicare Advantage Plans Work?, Medicare.gov, <https://www.medicare.gov/sign-up-change-plans/types-of-medicare-health-plans/medicare-advantage-plans/how-do-medicare-advantage-plans-work> (last visited Dec. 28, 2021). Plaintiffs allege that, under Medicare rules, healthcare providers who submit claims to Medicare must “certify that each claim complies with all Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute.” (United Am. Compl. ¶ 60; Humana Compl. ¶ 48). Plaintiffs also contend it is a violation of the federal anti-kickback statute for a drug manufacturer to waive a Medicare enrollee’s cost-sharing obligations, that is, his or her “premiums, deductibles, co-pays, or co-insurance.” (United Am. Compl. ¶ 56).

Plaintiffs allege Regeneron engaged in a years-long kickback scheme to promote EYLEA. Namely, plaintiffs allege Regeneron effectively waived patients’ co-pays for EYLEA

via coordinated donations to a purportedly independent charity, the Chronic Disease Fund (“CDF”), that, in turn, provided grants to patients specifically to cover EYLEA co-pays in violation of the federal anti-kickback statute. Plaintiffs further allege Regeneron worked with a consulting firm, the Lash Group, to establish the “EYLEA4U program,” which publicized and administered the grants offered by the CDF. According to plaintiffs, Regeneron’s conduct was designed to make EYLEA more attractive to patients than competitor drugs, even though it “is neither the most effective . . . drug, nor the least expensive.” (United Am. Compl. ¶¶ 30–38; accord Humana Compl. ¶¶ 23–27).

In addition, plaintiffs allege Regeneron knew it was violating the federal anti-kickback statute and concealed its conduct from the public, as well as from plaintiffs.

On June 24, 2020, the United States commenced the DOJ Action against Regeneron in the U.S. District Court for the District of Massachusetts, alleging Regeneron engaged in a kickback scheme to promote EYLEA in violation of the False Claims Act. (DOJ Doc. #1). Fact discovery closes in the DOJ Action on February 21, 2022, and expert discovery closes on July 14, 2022. (DOJ Doc. #99).

United commenced its action against Regeneron in this District on December 17, 2020. United asserts Regeneron’s kickback scheme “tainted all or most of the claims submitted to United’s Medicare plans for EYLEA from 2013” onwards, amounting to fraud upon United and tortious interference with its Medicare Advantage insurance policies. (United Am. Compl. ¶ 235). United further contends that, by concealing the kickbacks, Regeneron was engaged in a racketeering scheme and deceptive business practices. The first amended and operative complaint was filed on March 25, 2021, asserting claims for fraud, fraudulent concealment, tortious interference with contract, aiding and abetting tortious conduct, federal civil RICO

violations, conspiracy to commit federal civil RICO, unjust enrichment, and violations of state consumer-protection laws. Regeneron thereafter moved to dismiss or, in the alternative, stay the action pending resolution of the DOJ Action.

Humana commenced its action against Regeneron in this District on July 22, 2021, making the same allegations and asserting the same claims, as well as violations of state insurance-fraud law. Regeneron again moved to dismiss or, in the alternative, stay the action pending resolution of the DOJ Action.

Discovery has not begun in either case.

DISCUSSION

I. Legal Standard

“[T]he power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants.” Landis v. N. Am. Co., 299 U.S. 248, 254 (1936). To that end, courts have discretion to stay civil proceedings to “simplify the issues to be tried” and “promote economy of effort for all concerned.” Schiff v. Metzner, 331 F.2d 963, 964–65 (2d Cir. 1964).² The party seeking a stay “bears the burden of establishing its need.” Clinton v. Jones, 520 U.S. 681, 708 (1997).

Courts in this circuit generally consider the following five factors in deciding whether a stay is appropriate:

(1) the private interests of the plaintiffs in proceeding expeditiously with the civil litigation as balanced against the prejudice to the plaintiffs if delayed; (2) the private interests of and burden on the defendants; (3) the interests of the courts; (4) the interests of persons not parties to the civil litigation; and (5) the public interest.

² Unless otherwise indicated, case quotations omit all internal citations, quotation marks, footnotes, and alterations.

Kappel v. Comfort, 914 F. Supp. 1056, 1058 (S.D.N.Y. 1996). When “it is efficient for a trial court’s docket and the fairest course for the parties, a stay is proper, even in cases where the issues in [other pending] proceedings are not necessarily controlling on the action before the court.” Sikhs for Just. v. Nath, 893 F. Supp. 2d 598, 622 (S.D.N.Y. 2012).

In addition, “[t]he party moving for a stay ‘must make out a clear case of hardship or inequity in being required to go forward, if there is even a fair possibility that the stay for which he prays will work damage to some one else.’” Am. S.S. Owners Mut. Prot. & Indem. Ass’n v. Lafarge N. Am., Inc., 474 F. Supp. 2d 474, 482 (S.D.N.Y. 2007) (quoting Landis v. N. Am. Co., 299 U.S. at 255), aff’d sub nom. N.Y. Marine & Gen. Ins. Co., 599 F.3d 102 (2d Cir. 2010).

II. Analysis

Regeneron has demonstrated the balance of factors weighs in favor of a stay. The Court addresses each factor in turn below.

A. Private Interests of and Prejudice to Plaintiffs

Regeneron has shown a stay would minimally prejudice plaintiffs.

Although “[c]ourts are generally reluctant to stay proceedings because they are concerned with vindicating the plaintiff’s right to proceed with its case,” LaSala v. Needham & Co., 399 F. Supp. 2d 421, 428 (S.D.N.Y. 2005), this right must be “balanced against the prejudice to the plaintiff[]” resulting from any delay. Kappel v. Comfort, 914 F. Supp. at 1058.

As Regeneron points out, no discovery has been taken in the instant cases, meaning plaintiffs will not be prejudiced by the suspension of any discovery efforts. See HMT, Inc. v. Bell BCI Co., 2007 WL 295328, at *2 (W.D.N.Y. Jan. 30, 2007) (stay of second action would not prejudice plaintiff when the second action “is in its very early stages of preparation” but, in

the first action, “substantial amounts of time and expense have been invested in preparation by the parties and the Court”).³

Moreover, plaintiffs’ arguments to the contrary are unavailing.

For one, plaintiffs contend delaying discovery in these cases will prejudice them because “memories [will] fade, key witnesses [will] leave the company or pass away,” and generally that evidence may be “lost” or “grow[] stale.” (United Doc. #36 (“United Opp.”), at 34; Humana Doc. #31 (“Humana Opp.”), at 34). But Regeneron has been participating in discovery in the DOJ Action for months on the same issues in dispute here, which means relevant evidence is already being preserved.

For another, plaintiffs argue they will be prejudiced by a stay because they “will be forced . . . to continue paying EYLEA claims that [they] reasonably believe[]—but cannot yet definitively prove—to violate federal law and [their] contracts with [their] members.” (United Opp. at 34; Humana Opp. at 34). However, the DOJ Action will resolve whether Regeneron’s conduct with respect to EYLEA violates federal law, meaning any stay here will have no impact on plaintiffs’ payment schedule.

B. Private Interests of and Burdens on Regeneron

Regeneron has also shown that proceeding with these cases would be unfairly burdensome. In particular, Regeneron could be subject to inconsistent judgments in these cases and the DOJ Action if all proceed concurrently.

³ Regeneron counters that a delay will not prejudice plaintiffs because plaintiffs learned in February 2017 of the DOJ’s allegations against Regeneron and still waited over three years to commence these cases. This contradicts plaintiffs’ complaints, in which they allege they only learned about Regeneron’s purported scheme when the government commenced the DOJ Action in June 2020. Thus, the Court does not credit Regeneron’s argument in its analysis.

These cases and the DOJ Action rely on the same premise. In the DOJ Action, the United States alleges Regeneron orchestrated a kickback scheme to promote EYLEA. Here, plaintiffs allege:

- Fraudulent Concealment and Fraud (Count I). Regeneron knew healthcare providers were submitting EYLEA claims to plaintiffs that were “tainted by illegal kickbacks” and concealed that fact from plaintiffs, damaging plaintiffs. (United Am. Compl. ¶¶ 209–36; Humana Compl. ¶¶ 188–211).
- Tortious Interference with Contract (Count II). Plaintiffs’ customers were contractually required under their insurance policies to pay their cost-sharing obligations for EYLEA, and Regeneron “intentionally interfered” with those policies by effectively waiving those cost-sharing obligations through its kickback scheme. (United Am. Compl. ¶¶ 238–48; Humana Compl. ¶¶ 213–23).
- Aiding and Abetting Tortious Conduct (Count III). In the alternative to Count II, plaintiffs allege the CDF tortiously interfered with plaintiffs’ insurance policies, and Regeneron “provided substantial aid and encouragement” to the CDF by “fund[ing] the payments that the CDF made . . . to cover [plaintiffs’] cost-sharing responsibilities.” (United Am. Compl. ¶¶ 248–59; Humana Compl. ¶¶ 225–34).
- Violation of Civil RICO, 18 U.S.C. § 1962(c) (Count IV). By facilitating and concealing the kickback scheme, Regeneron, the CDF, and the Lash Group were an “association-in-fact” collectively engaged in “a pattern of racketeering activity.” (United Am. Compl. ¶¶ 261–77; Humana Compl. ¶¶ 236–55).
- Conspiracy to Violate Civil RICO, 18 U.S.C. § 1962(d) (Count V). By planning the kickback scheme with the CDF and the Lash Group, Regeneron conspired to violate the civil RICO statute. (United Am. Compl. ¶¶ 280–88; Humana Compl. ¶¶ 257–62).
- Unjust Enrichment (Count VI). Regeneron accepted payments from plaintiffs for EYLEA, but because of Regeneron’s kickback scheme, “it would be inequitable for Regeneron to retain” those payments. (United Am. Compl. ¶¶ 290–94; Humana Compl. ¶¶ 264–68).
- Violation of New York General Business Law § 349 and Other State Deceptive Trade Practices Law (Count VII). Regeneron concealed its kickback scheme from plaintiffs, and its deception caused plaintiffs to pay EYLEA claims, which violates Arizona, California, Colorado, Florida, Illinois, Michigan, Minnesota, Nebraska, Nevada, New Hampshire, New York, and North Carolina consumer-protection law. (United Am. Compl. ¶¶ 296–304; Humana Compl. ¶¶ 270–81).

- Violations of State Insurance Fraud Laws (Count VIII). By virtue of Regeneron's kickback scheme, claims for EYLEA were submitted to Humana with false or misleading information (namely, that the claims were not "tainted by illegal kickbacks"), in violation of Kentucky, Pennsylvania, and Tennessee insurance-fraud statutes. (Humana Compl. ¶¶ 283–89).

In other words, although plaintiffs' claims are not identical to the claims asserted in the DOJ Action, each claim hinges on an adjudication that Regeneron engaged in an illegal kickback scheme. Thus, both this Court and the district court in Massachusetts must determine whether Regeneron actually engaged in an illegal kickback scheme, and the two courts could potentially come to different conclusions. This weighs in favor of a stay. See, e.g., HMT, Inc. v. Bell BCI Co., 2007 WL 295328, at *2 (staying case brought by a subcontractor against general contractor pending resolution of a case brought against the same general contractor by a different subcontractor in the District of Maryland, finding "the burden on [defendant] will be significant since [defendant] will be forced to undergo unnecessary piecemeal litigation of similar issues, which could lead to inconsistent results"); cf. Evergreen Marine Corp. v. Welgrow Int'l Inc., 954 F. Supp. 101, 103–04 (S.D.N.Y. 1997) (staying case pending resolution of related Belgian proceeding to "minimize the risk of inconsistent judgments with respect to related claims").

C. Interests of the Courts

Regeneron has also demonstrated the interests of the courts weigh in favor of a stay.

Courts disfavor duplicative litigation. See Curtis v. Citibank, N.A., 226 F.3d 133, 138 (2d Cir. 2000). Further, courts may stay a later-filed action pending resolution of a substantially similar, but not identical, first-filed case "in light of the disfavored nature of duplicative litigation." See, e.g., Sensient Colors, Inc. v. Kohnstamm, 2008 WL 11456113, at *2 (S.D.N.Y. July 7, 2008) (staying civil case against individual shareholders pending resolution of first-filed case in the District of Minnesota against different individual shareholders).

As explained above, the issues in these cases and the DOJ Action significantly overlap. Plaintiffs' cases turn on whether Regeneron engaged in an illegal kickback scheme to promote EYLEA, which will be determined in the DOJ Action. A stay is appropriate pending resolution of an earlier-filed suit when "the claims at issue in the [second case] may well turn on determinations made in the [earlier-filed] suit." Royal Park Invs. SA/NV v. U.S. Bank Nat'l Ass'n, 356 F. Supp. 3d 287, 299 (S.D.N.Y. 2018); see, e.g., Trikona Advisors Ltd. v. Kai-Lin Chuang, 2013 WL 1182960, at *4 (E.D.N.Y. Mar. 20, 2013) (staying case against personal assistant pending resolution of first-filed case in Connecticut federal court against the personal assistant's employer, noting "[w]hile the Connecticut action 'may not settle every question of fact and law' at issue in [plaintiff]'s suit against [the personal assistant], it will 'in all likelihood settle many and simplify them all.'" (quoting Landis v. N. Am. Co., 299 U.S. at 256)).

D. Interests of Persons Not Parties to the Civil Litigation

Regeneron does not address the impact of a stay on persons not parties to these cases. As a result, this factor weighs against issuance of a stay.

E. Public Interest

Finally, Regeneron has established the public interest is served by a stay.

For one, the public interest is served "by promoting the efficient use of judicial resources and minimizing the possibility of conflicts between different courts." Nuccio v. Duve, 2015 WL 1189617, at *5 (N.D.N.Y. Mar. 16, 2015); cf. Catskill Mountains Chapter of Trout Unlimited, Inc. v. U.S. Env't Prot. Agency, 630 F. Supp. 2d 295, 304–05 (S.D.N.Y. 2009) (staying challenge to promulgation of EPA regulation pending a nonbinding Eleventh Circuit decision on "virtually identical" EPA regulation in the interest of judicial economy).

For another, although the DOJ Action is not a criminal prosecution, it is a civil enforcement proceeding brought by the government, which represents the public interest. Thus, plaintiffs' interests will likely be protected in the DOJ Action. Cf. Louis Vuitton Malletier S.A. v. LY USA, Inc., 676 F.3d 83, 101 (2d Cir. 2012) (noting criminal prosecution of plaintiff's employees for trafficking in and smuggling counterfeit goods promotes the same interest as plaintiff's civil lawsuit against those employees for trademark counterfeiting and infringement).

* * * * *

Whether to stay these cases is a close question. Plaintiffs possess a "strong interest in proceeding with [their] litigation," Exp.-Imp. Bank v. Hi-Films S.A. de C.V., 2010 WL 3743826, at *12 (S.D.N.Y. Sep. 24, 2010), and the DOJ Action may not conclude for years. But the Court believes any prejudice to plaintiffs resulting from a stay will be minimal, and because of the risk of inconsistent judgments, the interests of Regeneron, the courts, and the public weigh in favor of a stay. Moreover, judicial efficiency is in the interest of the courts and the public, and the degree of overlap between these cases and the DOJ Action means that a resolution in the DOJ Action would greatly simplify, if not completely resolve, these cases. In other words, "the public interest in prompt adjudication is counterbalanced by its interest in conserving judicial resources." Royal Park Invs. SA/NV v. U.S. Bank Nat'l Ass'n, 356 F. Supp. 3d at 299. And finally, the government represents the public in the DOJ Action, which means plaintiffs' interests will likely be protected in the DOJ Action.

Accordingly, the balance of factors weighs in favor of a stay.

CONCLUSION

The motions to stay are GRANTED.

All proceedings in these two actions are hereby STAYED pending further Court order. Regeneron shall notify the Court within ten days of the resolution of the DOJ Action, and, in any event, shall update the Court as to the status of the DOJ Action by June 30, 2022.

The motions to dismiss are TERMINATED without prejudice to renewal following the conclusion of the stays.

The Clerk is instructed to terminate the motions. (Doc. #32 in case number 20 CV 10664; Doc. #20 in case number 21 CV 6245).

Dated: December 28, 2021
White Plains, NY

SO ORDERED:

A handwritten signature in black ink, appearing to read 'Vincent Briccetti', written over a horizontal line.

Vincent L. Briccetti
United States District Judge